Second Regular Session 113th General Assembly (2004)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2003 Regular Session of the General Assembly.

HOUSE ENROLLED ACT No. 1251

AN ACT concerning prescription drugs.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 16-28-11-4 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2004]: **Sec. 4. A health facility that possesses unused medication that meets the requirements of IC 25-26-13-25(i)(1) through IC 25-26-13-25(i)(6):**

(1) shall return medication that belonged to a Medicaid recipient; and

(2) may return other unused medication;

to the pharmacy that dispensed the medication.

SECTION 2. IC 25-26-13-25, AS AMENDED BY P.L.182-2003, SECTION 4, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2004]: Sec. 25. (a) All original prescriptions, whether in written or electronic format, shall be numbered and maintained in numerical and chronological order, or in a manner approved by the board and accessible for at least two (2) years in the pharmacy. A prescription transmitted from a practitioner by means of communication other than writing must immediately be reduced to writing or recorded in an electronic format by the pharmacist. The files shall be open for inspection to any member of the board or its duly authorized agent or representative.

(b) Except as provided in subsection (c), ~~before the expiration of subsection (c) on June 30, 2003,~~ a prescription for any drug, the label of which bears either the legend, "Caution: Federal law prohibits dispensing without prescription" or "Rx Only", may not be refilled without written or oral authorization of a licensed practitioner.

(c) A prescription for any drug, the label of which bears either the legend, "Caution: Federal law prohibits dispensing without prescription" or "Rx Only", may be refilled by a pharmacist one (1) time without the written or oral authorization of a licensed practitioner if all of the following conditions are met:

(1) The pharmacist has made every reasonable effort to contact the original prescribing practitioner or the practitioner's designee for consultation and authorization of the prescription refill.

(2) The pharmacist believes that, under the circumstances, failure to provide a refill would be seriously detrimental to the patient's health.

(3) The original prescription authorized a refill but a refill would otherwise be invalid for either of the following reasons:

(A) All of the authorized refills have been dispensed.

(B) The prescription has expired under subsection (f).

(4) The prescription for which the patient requests the refill was:

(A) originally filled at the pharmacy where the request for a refill is received and the prescription has not been transferred for refills to another pharmacy at any time; or

(B) filled at or transferred to another location of the same pharmacy or its affiliate owned by the same parent corporation if the pharmacy filling the prescription has full access to prescription and patient profile information that is simultaneously and continuously updated on the parent corporation's information system.

(5) The drug is prescribed for continuous and uninterrupted use and the pharmacist determines that the drug is being taken properly in accordance with IC 25-26-16.

(6) The pharmacist shall document the following information regarding the refill:

(A) The information required for any refill dispensed under subsection (d).

(B) The dates and times that the pharmacist attempted to contact the prescribing practitioner or the practitioner's designee for consultation and authorization of the prescription refill.

(C) The fact that the pharmacist dispensed the refill without the authorization of a licensed practitioner.

(7) The pharmacist notifies the original prescribing practitioner of the refill and the reason for the refill by the practitioner's next business day after the refill has been made by the pharmacist.

(8) Any pharmacist initiated refill under this subsection may not be for more than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day. However, a pharmacist may dispense a drug in an amount greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day if:

(A) the drug is packaged in a form that requires the pharmacist to dispense the drug in a quantity greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day; or

(B) the pharmacist documents in the patient's record the amount of the drug dispensed and a compelling reason for dispensing the drug in a quantity greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day.

(9) Not more than one (1) pharmacist initiated refill is dispensed under this subsection for a single prescription.

(10) The drug prescribed is not a controlled substance.

A pharmacist may not refill a prescription under this subsection if the practitioner has designated on the prescription form the words "No Emergency Refill".

(d) When refilling a prescription, the refill record shall include:

(1) the date of the refill;

(2) the quantity dispensed if other than the original quantity; and

(3) the dispenser's identity on:

(A) the original prescription form; or

(B) another board approved, uniformly maintained, readily retrievable record.

(e) The original prescription form or the other board approved record described in subsection (d) must indicate by the number of the original prescription the following information:

(1) The name and dosage form of the drug.

(2) The date of each refill.

(3) The quantity dispensed.

(4) The identity of the pharmacist who dispensed the refill.

(5) The total number of refills for that prescription.

(f) A prescription is valid for not more than one (1) year after the original date of issue.

(g) A pharmacist may not knowingly dispense a prescription after the demise of the practitioner, unless in the pharmacist's professional judgment it is in the best interest of the patient's health.

(h) A pharmacist may not knowingly dispense a prescription after the demise of the patient.

(i) A pharmacist or a pharmacy shall not resell, reuse, or redistribute a medication that is returned to the pharmacy after being dispensed unless the medication:

(1) was dispensed to a patient:

(A) residing in an institutional facility (as defined in ~~856 IAC 1-28-1(a)).~~ **856 IAC 1-28.1-1(6)); or**

(B) in a hospice program under IC 16-25;

(2) was properly stored and securely maintained according to sound pharmacy practices;

(3) is returned unopened and:

(A) was dispensed in the manufacturer's original:

(i) bulk, multiple dose container with an unbroken tamper resistant seal; or

(ii) unit dose package; or

(B) was packaged by the dispensing pharmacy in a:

(i) multiple dose blister container; or

(ii) unit dose package;

(4) was dispensed by the same pharmacy as the pharmacy accepting the return;

(5) is not expired; and

(6) is not a controlled substance (as defined in IC 35-48-1-9), unless the pharmacy holds a Type II permit (as described in ~~IC 25-26-13-17).~~ **section 17 of this chapter).**

(j) A pharmacist may use the pharmacist's professional judgment as to whether to accept medication for return under ~~subsection (i).~~ **this section.**

(k) A pharmacist who violates subsection (c) commits a Class A infraction.

SECTION 3. IC 25-26-16.5 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2004]:

Chapter 16.5. Drug Regimens in Health Facilities

Sec. 1. This chapter applies to a health facility licensed under IC 16-28.

Sec. 2. (a) As used in this chapter, "attending physician" means a physician licensed under IC 25-22.5 who is responsible for the ongoing health care of an individual who resides in a health facility.

(b) The medical director of a health facility to which the individual is admitted may not serve as the individual's attending physician unless the medical director meets the requirements set forth in subsection (a).

Sec. 3. As used in this chapter, "protocol" means a policy, procedure, or protocol of a health facility concerning the adjustment of a patient's drug regimen as allowed under this chapter by a pharmacist licensed under this article.

Sec. 4. As used in this chapter, "therapeutic alternative" means a drug product that:

(1) has a different chemical structure from;

(2) is of the same pharmacological or therapeutic class as; and

(3) usually can be expected to have similar therapeutic effects and adverse reaction profiles when administered to patients in therapeutically equivalent doses as;

another drug.

Sec. 5. For purposes of this chapter, a pharmacist adjusts a drug regimen if the pharmacist:

(1) changes the duration of treatment for a current drug therapy;

(2) adjusts a drug's strength, dosage form, frequency of administration, or route of administration;

(3) discontinues the use of a drug; or

(4) adds a drug to the treatment regimen.

Sec. 6. At the time an individual is admitted to a health facility that has adopted a protocol under this chapter, the individual's attending physician shall signify in writing in the form and manner prescribed by the health facility whether the protocol applies in the care and treatment of the individual.

Sec. 7. (a) A pharmacist may adjust the drug therapy regimen of the individual under:

(1) the written authorization of the individual's attending physician under section 6 of this chapter;

(2) the health facility's protocols; and

(3) this chapter.

(b) The pharmacist shall review the appropriate medical records of the individual to determine whether the attending

physician has authorized the use of a specific protocol before the pharmacist adjusts the individual's drug therapy regimen.

(c) Notwithstanding subsection (a), if a protocol involves parenteral nutrition of the patient, the pharmacist shall communicate with the attending physician to receive approval to begin the protocol. The pharmacist shall document the authorization of the attending physician to use the protocol immediately in the individual's medical record.

Sec. 8. If a health facility elects to implement, revise, or renew a protocol under this chapter, the health facility shall establish a drug regimen review committee consisting of:

(1) the health facility's medical director;

(2) the health facility's director of nursing; and

(3) a consulting pharmacist licensed under this article;

for the implementation, revision, or renewal of a protocol.

Sec. 9. Except for the addition or deletion of authorized physicians and pharmacists, a modification to a written protocol requires the initiation of a new protocol.

Sec. 10. (a) A protocol of a health facility developed under this chapter must be:

(1) based on clinical considerations; and

(2) reviewed by the health facility's drug regimen committee at least quarterly.

(b) A protocol of a health facility developed under this chapter may not:

(1) prohibit the attending physician from approving only specific parts of a protocol; or

(2) provide for an adjustment to an individual's drug regimen for the sole purpose of achieving a higher reimbursement for the substituted drug therapy than what would have been received for the original drug therapy ordered by the attending physician.

Sec. 11. A protocol developed under this chapter must include the following:

(1) The identification of:

(A) the individual whose drug regimen may be adjusted;

(B) the attending physician who is delegating the authority to adjust an individual's drug regimen; and

(C) the pharmacist who is authorized to adjust the individual's drug regimen.

(2) The attending physician's diagnosis of the individual's:

(A) condition; or

(B) disease state;

whose drug regimen may be adjusted.

(3) A statement regarding:

(A) the types and:

(i) categories; or

(ii) therapeutic classifications;

of medication, including the specific therapeutic alternatives that may be substituted for a drug prescribed by a physician;

(B) the minimum and maximum dosage levels within the types and:

(i) categories; or

(ii) therapeutic classifications;

of medications described in clause (A);

(C) the dosage forms;

(D) the frequency of administration;

(E) the route of administration;

(F) the duration of the administration of the drug regimen and any adjustment to the drug regimen; and

(G) exceptions to the application of the drug regimen or the adjustment to the drug regimen;

for which the pharmacist may adjust the individual's drug regimen.

(4) A requirement that:

(A) the individual's medical records be available to both the individual's attending physician and the pharmacist; and

(B) the procedures performed by the pharmacist relate to a disease or condition for which the patient has been under the attending physician's medical care.

Sec. 12. A protocol developed under this chapter that is implemented for a Medicaid recipient must comply with any statutes, regulations, and procedures under the state Medicaid program relating to the preferred drug list established under IC 12-15-35-28.

Sec. 13. If a protocol developed under this chapter allows a pharmacist to substitute a therapeutic alternative for the drug prescribed by the individual's attending physician, the attending physician's authorization of the substitution is valid only for the duration of the prescription or drug order.

Sec. 14. This chapter does not allow a pharmacist to substitute a therapeutic alternative for the drug prescribed by the individual's attending physician unless the substitution is authorized by the attending physician under a valid protocol under this chapter.

Sec. 15. The individual's attending physician:

(1) shall review a protocol approved and implemented for a patient of the physician at the physician's next visit to the health facility, and at each subsequent visit of the physician to the health facility; and

(2) may at any time modify or cancel a protocol by entering the modification or cancellation in the individual's medical record.

Sec. 16. (a) Documentation of protocols must be maintained in a current, consistent, and readily retrievable manner.

(b) After making an adjustment to an individual's drug regimen, the pharmacist shall immediately document the adjustment in the patient's medical record.

(c) The pharmacist shall notify the individual's attending physician of an adjustment at least one (1) business day before the adjustment is made.

Sec. 17. (a) This chapter does not modify the requirements of other statutes relating to the confidentiality of medical records.

(b) This chapter does not make any other licensed health care provider or pharmaceutical manufacturer liable for the actions of a pharmacist carried out under this section.

(c) A physician who approves the use of a protocol under this chapter and a pharmacist who adjusts a drug regimen of a patient pursuant to a protocol under this chapter do not violate IC 25-22.5-1-2(d).

Sec. 18. A pharmacist who violates this chapter is subject to discipline under IC 25-1-9.

SECTION 4. IC 25-26-20 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2004]:

Chapter 20. Regional Drug Repository Program

Sec. 1. The definitions in IC 25-26-13-2 apply throughout this chapter.

Sec. 2. As used in this chapter, "nonprofit health clinic" means any of the following:

(1) A federally qualified health center (as defined in 42 U.S.C.

1396d(l)(2)(B)).

(2) A rural health clinic (as defined in 42 U.S.C. 1396d(l)(1)).

(3) A nonprofit health clinic that provides medical care to patients who are indigent, uninsured, or underinsured.

Sec. 3. (a) The board may organize a voluntary regional drug repository program to collect and redistribute drugs to nonprofit health clinics.

(b) The board may enter into a voluntary agreement with any of the following to serve as a regional drug repository:

(1) A pharmacist or pharmacy.

(2) A wholesale drug distributor.

(3) A hospital licensed under IC 16-21.

(4) A health care facility (as defined in IC 16-18-2-161).

(5) A nonprofit health clinic.

(c) A regional drug repository may not receive compensation for participation in the program.

Sec. 4. (a) Except as provided in subsections (b) and (c), unadulterated drugs that meet the requirements set forth in IC 25-26-13-25(i) may be donated without a prescription or drug order to the regional drug repository program by the following:

(1) A pharmacist or pharmacy.

(2) A wholesale drug distributor.

(3) A hospital licensed under IC 16-21.

(4) A health care facility (as defined in IC 16-18-2-161).

(5) A hospice.

(6) A practitioner.

(b) An unadulterated drug that:

(1) was returned under IC 25-26-13-25; and

(2) was prescribed for a Medicaid recipient;

may not be donated under this section unless the Medicaid program has been credited for the product cost of the drug as provided in policies under the Medicaid program.

(c) A controlled drug may not be donated under this section.

Sec. 5. (a) A drug that is given by a regional drug repository to a nonprofit health clinic may not be:

(1) sold; or

(2) given to a patient, except upon a practitioner's prescription or drug order.

(b) An individual who is eligible to participate in:

(1) the state Medicaid program under IC 12-15; or

(2) a program that:

(A) provides a prescription drug benefit; and

(B) is funded in whole or in part by state funds;

is not eligible to receive a drug donated under the voluntary regional drug repository program organized under section 3 of this chapter.

Sec. 6. (a) The following are not subject to liability under IC 34-20-2-1:

(1) A person or entity who donates a drug to a regional drug repository program under this chapter in accordance with rules adopted by the board under section 7 of this chapter.

(2) A non-profit health clinic or practitioner who accepts or dispenses a drug under the regional drug repository program in accordance with rules adopted by the board under section 7 of this chapter.

(3) A regional drug repository that distributes a drug under the program in accordance with rules adopted by the board under section 7 of this chapter.

(b) Except in cases of negligence or willful misconduct by the manufacturer, a drug manufacturer is not subject to liability under IC 34-20-2-1 for a claim arising from a drug that is donated, accepted, or dispensed under this chapter to the user or the consumer.

Sec. 7. The board may adopt rules under IC 4-22-2 to:

(1) establish standards and procedures for accepting, storing, and dispensing drugs donated under this chapter;

(2) establish the types of drugs that may be donated; and

(3) administer this chapter.

SECTION 5. IC 34-30-2-101.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2004]: **Sec. 101.5. IC 25-26-20-6 (Concerning drugs donated to a regional drug repository program).**

SECTION 6. [EFFECTIVE JULY 1, 2004] **(a) As used in this SECTION, "office" refers to the office of Medicaid policy and planning established by IC 12-8-6-1.**

(b) Before January 1, 2005, the office shall review the process of returning unused medication under IC 25-26-13-25, as amended by this act, and the process of reimbursing the office for unused medication of a Medicaid recipient. The office may consider in the office's review information provided by pharmacies that provide long term care pharmacy services. Beginning December 31, 2004, the office may review the process of returning unused medication

when the office determines that a review is necessary.

(c) Before October 1, 2004, the office shall provide any information gathered under subsection (b) to the health finance commission established by IC 2-5-23-3. Before November 1, 2004, the health finance commission shall review the process of returning unused medication under IC 25-26-13-25, including the reimbursement to the office for the unused medication of a Medicaid recipient.

(d) This SECTION expires December 31, 2009.

SECTION 7. [EFFECTIVE UPON PASSAGE] **(a) The Indiana prescription drug advisory committee is established to:**

(1) study pharmacy benefit programs and proposals, including programs and proposals in other states;

(2) make initial and ongoing recommendations to the governor for programs that address the pharmaceutical costs of low income senior citizens; and

(3) review and approve changes to a prescription drug program that is established or implemented under a Medicaid waiver that uses money from the Indiana prescription drug account established by IC 4-12-8-2.

(b) The committee consists of eleven (11) members appointed by the governor and four (4) legislative members. Members serving on the committee established by P.L.291-2001, SECTION 81, before its expiration on December 31, 2001, continue to serve. The term of each member expires December 31, 2006. The members of the committee appointed by the governor are as follows:

(1) A physician with a specialty in geriatrics.

(2) A pharmacist.

(3) A person with expertise in health plan administration.

(4) A representative of an area agency on aging.

(5) A consumer representative from a senior citizen advocacy organization.

(6) A person with expertise in and knowledge of the federal Medicare program.

(7) A health care economist.

(8) A person representing a pharmaceutical research and manufacturing association.

(9) A township trustee.

(10) Two (2) other members as appointed by the governor.

The four (4) legislative members shall serve as nonvoting members. The speaker of the house of representatives and the president pro

tempore of the senate shall each appoint two (2) legislative members, who may not be from the same political party, to serve on the committee.

(c) The governor shall designate a member to serve as chairperson. A vacancy with respect to a member shall be filled in the same manner as the original appointment. Each member is entitled to reimbursement for traveling expenses and other expenses actually incurred in connection with the member's duties. The expenses of the committee shall be paid from the Indiana prescription drug account established by IC 4-12-8-2. The office of the secretary of family and social services shall provide staff for the committee. The committee is a public agency for purposes of IC 5-14-1.5 and IC 5-14-3. The committee is a governing body for purposes of IC 5-14-1.5.

(d) The committee shall make program design recommendations to the governor and the office of the secretary of family and social services to coordinate the Indiana prescription drug program administered under IC 12-10-16-3 with the federal Medicare Prescription Drug and Improvement and Modernization Act of 2003, and to ensure that the program does not duplicate benefits provided under the federal law. In making recommendations, the committee shall consider the following:

(1) Eligibility criteria, including any changes in income limits.

(2) Benefit structure, including determining if the program will assume any of a program recipient's premiums or cost sharing requirements required by federal law.

(3) Cost sharing requirements, including whether the program should include a requirement for copayments or premium payments.

(4) Marketing and outreach strategies.

(5) Administrative structure and delivery systems.

(6) Evaluation.

(7) Coordination with existing private or public pharmaceutical assistance programs available to an individual in Indiana.

(e) The recommendations shall address the following:

(1) Cost effectiveness of program design.

(2) Strategies to minimize crowd out of private insurance.

(3) Reasonable balance between maximum eligibility levels and maximum benefit levels.

(4) Feasibility of a health care subsidy program where the

amount of the subsidy is based on income.

(5) Advisability of entering into contracts with health insurance companies to administer the program.

(f) The committee shall submit its recommended changes to the governor and the office of the secretary of family and social services before:

(1) July 1, 2004, for program changes related to the Medicare discount program; and

(2) September 1, 2005, for program changes related to the part D Medicare drug benefit.

(g) This SECTION expires December 31, 2006.

SECTION 8. THE FOLLOWING ARE REPEALED [EFFECTIVE UPON PASSAGE]: P.L.106-2002, SECTION 1; P.L.107-2002, SECTION 35; P.L.224-2003, SECTION 68.

SECTION 9. **An emergency is declared for this act.**

Speaker of the House of Representatives

President of the Senate

President Pro Tempore

Approved:

Governor of the State of Indiana